

REMARKS

This is in response to the Office Action of June 14, 2007. Claims 1-6 are pending in the present application.

In the Office Action, the Examiner: (1) rejected claims 1-3 and 6 on the ground of non-statutory double patenting over claims 1, 3, 4, 7 and 8 of U.S. Patent No. 7,041,076 to Westberg et al. and; (2) rejected claims 1-6 under 35 USC 103 as being obvious over US 5,482,440 to Dennehey et al. in view of US 4,750,868 to Lundback.

At the outset, Applicants would like to thank the Examiner for considering the references cited in the Information Disclosure Statements submitted on April 20, 2004 and June 10, 2004.

The Pending Claims Would Not Have Been Obvious Over US 5,482,440 To Dennehey et al. In View Of US 4,750,868 To Lundback

Turning first to the rejection of claims 1-6 under 35 USC § 103, it is respectfully submitted that independent claim 1 and the respective dependent claims would not have been obvious over the cited references.

Specifically, independent claim 1 requires, among other things, a blood processing system comprising a filter for removing leukocytes from blood, first and second fluid pressure actuated pump stations, and a fluid pressure actuator. The actuator operates to selectively apply fluid pressure pump strokes in tandem to the first and second pump stations to convey fluid from a source to the filter. The fluid pressure actuator includes a control function to switch between a first flow mode, in which the

pump strokes draw a fluid volume into the first pump station from the source and expel a fluid volume from the second pump station to the filter, and a second flow mode, in which the pump strokes draw a fluid volume into the second pump station from the source and expel a fluid volume from the first pump station to the filter. The control function operates to synchronize the pump strokes so that fluid flow from the source is essentially continuous while fluid flow to the filter is pulsatile. A blood processing system having two alternating pump stations as presently claimed serves to reduce overall processing time, as fluid is continuously conducted into a drawing pump station throughout the procedure. See page 31 of the published application, para. [0482] through [0483].

The cited Dennehey patent does not describe or suggest a blood processing system comprising (1) a blood processing system comprising first and second fluid pressure actuated pump stations, (2) a blood processing system in which a fluid pressure actuator operates to selectively apply fluid pressure pump strokes in tandem to first and second pump stations to convey fluid from a source to a filter, (3) a fluid pressure actuator that includes a control function to switch between a first flow mode, in which pump strokes draw a fluid volume into a first pump station from a source and expel a fluid volume from a second pump station to a filter, and a second flow mode, in which pump strokes draw a fluid volume into a second pump station from a source and expel a fluid volume from a first pump station to a filter, or (4) a control function operating to synchronize pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a filter is pulsatile. Applicants discuss each, in turn, below.

Dennehey Does Not Describe A Blood Processing System Comprising First And Second Fluid Pressure Actuated Pump Stations

First, Dennehey does not describe a blood processing system comprising first and second fluid pressure actuated pump stations as required by claim 1. For example, the pumping of fluid throughout the illustrated blood processing system is accomplished by pneumatically actuated pump stations PP(N). The pump stations may be contained, for example, within a cassette, which provides a centralized, programmable, integrated platform for all the pumping and valving functions required for a given blood processing procedure. See page 4, para. [0078]. In the illustrated embodiment, various pump actuators convey positive or negative pneumatic pressures to flex a diaphragm overlying the front of a cassette to operate the pump stations (PP1 to PP4) and therefore move blood and processing liquid through the pump stations. See page 6, para [0119]. In particular, with the application of positive and negative fluid pressures upon certain regions of the diaphragm, liquid is expelled out of the pump stations (by positive pressure) or drawn into the pump stations (by negative pressure) and otherwise moved throughout the fluid circuit.

In contrast, Dennehey discloses a fluid circuit including multiple pump stations A, B and C, and peristaltic pumps that operate on external tubing loops outside of each of the pump stations. The tube loops 134 and 136 are engaged by peristaltic pump rotors on the centrifuge assembly to convey liquid throughout the system. (See col. 17, lines 9-17 and col. 23 line 62 through col. 24, line 21 and Fig. 6). Further, various electrically actuated solenoid pistons serve to open and close various valves and thereby direct fluid flow as it is pumped by the peristaltic pumps. (See col. 23, lines 39-55). Thus,

Dennehey does not disclose or suggest first and second fluid pressure actuated pump stations as required by claim 1.

Dennehey Does Not Describe A Blood Processing System In Which A Fluid Pressure Actuator Operates To Selectively Apply Fluid Pressure Actuated Pump Strokes In Tandem To First And Second Pump Stations

Second, Dennehey does not describe a blood processing system in which a fluid pressure actuator operates to selectively apply fluid pressure pump strokes in tandem to first and second pump stations to convey fluid from a source to a filter. Instead, Dennehey describes various independent pump stations A, B and C, which work only on the fluid flow paths with which they are associated. As described in Dennehey, only pump station 22C is in communication with the flow path containing a leukocyte filter 82. Pump station 22C serves to pump fluid from a first stage processing compartment 34 to a leukocyte filter 82 before it enters the second stage processing compartment. See col. 18, line 9-21 (describing the single needle circuit) and col. 19, line 65 through col. 20, line 5 (describing the double needle circuit). Pump station 22C simply operates on the fluid flow path containing filter 82, alone and independently from pump stations A and B, to pump fluid from the first stage separation chamber to the filter. Thus, there is no "second" pump station in which pump strokes could operate on, in tandem with a "first" pump station (i.e. 22 C), to convey fluid from a source to a filter as required by claim 1.

Dennehey Does Not Describe A Fluid Pressure Actuator Including A Control Function To Switch Between A First Mode and A Second Mode

Third, Dennehey does not describe a fluid pressure actuator that includes a control function to switch between a first flow mode, in which pump strokes draw a fluid volume into a first pump station from a source and expel a fluid volume from a second pump station to a filter, and a second flow mode, in which pump strokes draw a fluid volume into a second pump station from a source and expel a fluid volume from a first pump station to a filter, as required by claim 1.

For example, as described in further detail in the specification, universal pump stations PP3 and PP4, in tandem, serve as a general purpose, donor interface pump. The fluid pressure actuator switches between a first and second flow mode, allowing, for example, pump stations PP3 and PP4 to “toggle” or alternate draw and expel functions. See page 34, para. [0531]. The expelling pump station performs, for example, a one second expel cycle at the beginning of the draw cycle of the drawing pump, and then rests for the remaining nine seconds of the draw cycle. The pump stations then switch draw and expel functions. These synchronized pump strokes allow fluid flow from the source to be essentially continuous, which has the advantage, for example, of reducing overall processing time, as fluid is continuously conducted into a drawing pump station throughout the procedure. (See specification, page 34, para. [0527] through page 35, para. [0542]). In addition, synchronizing the pump strokes may have an advantage of allowing blood to be simultaneously drawn from and returned to a donor through a single phlebotomy needle. See page 31, para. [0485].

It is respectfully submitted that the above-described features are not found nor contemplated in Dennehey. The Examiner points to the "draw cycle" and "return cycle" in Dennehey as corresponding to the claimed feature of a first flow mode and second flow mode. However, the draw and return cycles of Dennehey are significantly different from the claimed feature of a fluid pressure actuator that includes a control function to switch a given fluid actuated pump station between first and second flow modes. Specifically, Dennehey describes a draw cycle which draws whole blood from a donor and a return cycle which returns red blood cells to the donor. Each of these "draw" and "return" cycles must operate fully and independently from one another, because blood cannot be drawn from and returned to a donor at the same time through the same flow path. Thus, only when an entire "draw" cycle must is complete can the "return" cycle begin. No matter how the system in Dennehey is programmed or what blood processing procedure is intended to be performed, Dennehey does not describe a fluid pressure actuator including a control function as presently claimed, nor is Dennehey even capable of switching between a first flow mode, in which pump strokes draw a fluid volume into a first pump station from a source and expel a fluid volume from a second pump station to a filter, and a second flow mode, in which pump strokes draw a fluid volume into a second pump station from a source and expel a fluid volume from a first pump station to a filter as required by claim 1.

Dennehey Does Not Describe A Fluid Pressure Actuator That Synchronizes Pump Strokes So That Fluid Flow From The Source Is Continuous While Fluid Flow To The Filter Is Pulsatile

Fourth, Dennehey does not describe a control function operating to synchronize pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a filter is pulsatile, and the Examiner expressly acknowledges this fact in the Office Action of June 14, 2007. Further, the Lundback '868 patent does not disclose any of the subject matter missing from the Dennehey patent and is not properly combinable with Dennehey to render the claimed subject matter obvious. As noted above, Dennehey does not describe various structural features as set forth in the pending claims. Further, and as acknowledged by the Office Action, Dennehey does not disclose a fluid pressure actuator including a control function that synchronizes pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a filter is pulsatile. Accordingly, even if one were to combine the Lundback system, which describes generally a *single* pump that can be used in industry, mining, and the like, the resulting device would still not have the features of the claimed blood processing system in which a fluid pressure actuator operates to selectively apply fluid pressure pump strokes in tandem to *first and second* pump stations to convey fluid from a source to a filter.

Therefore, it is submitted that it would not have been obvious to one skilled in the art to combine the features of the Dennehey patent with the pump described in Lundback to reach the present invention.

Conclusion Regarding Non-Obviousness

Accordingly, it is respectfully submitted that there is no description or suggestion in Dennehey of (1) a blood processing system comprising first and second fluid pressure actuated pump stations, (2) a blood processing system in which a fluid pressure actuator operates to selectively apply fluid pressure pump strokes in tandem to first and second pump stations to convey fluid from a source to a filter, (3) a fluid pressure actuator that includes a control function to switch between a first flow mode, in which pump strokes draw a fluid volume into a first pump station from a source and expel a fluid volume from a second pump station to a filter, and a second flow mode, in which pump strokes draw a fluid volume into a second pump station from a source and expel a fluid volume from a first pump station to a filter, or (4) a control function operating to synchronize pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a filter is pulsatile as required by claim 1.

For the reasons above, it is respectfully submitted that claims 1-6 would not have been obvious over Dennehey et al. either alone or in combination with the Lundback '868 patent. Accordingly, the withdrawal of the rejections and reconsideration and allowance of the claims are respectfully requested.

Obviousness-Type Double Patenting

Applicants now turn to the rejection of claims 1-3 and 6 on the ground of non-statutory double patenting over claims 1, 3, 4, 7 and 8 of U.S. Patent No. 7,041,076 to Westberg et al. A non-statutory double patenting rejection may be overcome by the filing of a Terminal Disclaimer. See MPEP § 804.02. Applicant notes that at the time the invention claimed in this application was made, it was owned by the same person,

i.e. Baxter International Inc. This application has been subsequently assigned from Baxter International Inc. to Fenwal, Inc. The assignment of this application to Baxter International Inc. is recorded at Reel 010427/Frame 0855 and the subsequent assignment to Fenwal, Inc., is recorded at Reel 019129/Frame 0001. A Terminal Disclaimer based on the cited reference is being submitted herewith. Applicants believe that submission of this Terminal Disclaimer places this application in condition for allowance.

Clarification of Priority Claim

Finally, Applicants have clarified and updated the priority claim. Specifically, the original priority claim to U.S. application Serial No. 9/390,265 filed September 3, 1999 and to U.S. application Serial No. 09/390,268 filed September 3, 1999 is amended to state that this application is a divisional of the '265 application and that the '265 application has issued as Patent No. 6,723,062. The claim of priority to the '268 application is deleted as unnecessary.

Respectfully submitted,

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